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**DOCKET NUMBER**  
**PROPOSED RULE PR 110**  
**(69FR 55785)**

Henry H. Kramer, Ph.D., FACNP  
*Executive Director*

DOCKETED  
USNRC

November 29, 2004

November 29, 2004 (1:09pm)

Secretary  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001  
Attn: Rulemakings and Adjudications Staff

OFFICE OF SECRETARY  
RULEMAKINGS AND  
ADJUDICATIONS STAFF

**RE: Export and Import of Nuclear Equipment and Radioactive Materials: Security Policies**  
**RIN 3150-AH44**  
**FR Vol. 69, No. 179. September 16, 2004**

Gentlemen:

These comments concerning the notice of proposed rulemaking to amend the regulations pertaining to the security of export and import of nuclear equipment and radioactive materials are submitted on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR). CORAR members include manufacturers and shippers of diagnostic and therapeutic radiopharmaceuticals, life science research radiochemicals and sealed sources used in therapy, diagnostic imaging and calibration of instrumentation used in medical applications. CORAR recognizes the need for NRC to promote the common defense and security by updating its regulations to reflect the actions taken globally to achieve harmonization. CORAR provides the following comments to address in general the nature of the amendments as well as specific aspects of the proposed rule.

1. Scope and Applicability

We understand and appreciate the support provided by NRC in the effort to revise the IAEA Code of Conduct and we share the interest to take a harmonized approach to ensure a level playing field for commerce. Our industry is comprised of companies that have global supply chains and distribute products internationally so the implications of additional licensing requirements can be significant. It is in this context that we point out the fundamental discrepancy between the scope of materials covered in the Proposed Rule and those in the IAEA Code of Conduct.

Template = SECY-067

SECY-02

Specifically, the proposed NRC changes would apply to export and import shipments of radioactive *material* whereas the IAEA Code of Conduct applies to *sealed radioactive sources*, defined as radioactive material permanently sealed in capsules or closely bonded in a solid form. With this fundamental difference in scope of applicability, there is the potential for disagreement between States regarding how shipments may be authorized. This difference, therefore, needs to be addressed in this rulemaking.

## 2. Compatibility with other NRC Rulemaking

As the NRC undertakes a separate rulemaking regarding the Draft Security Measures for Transport of Radioactive Material of Concern, it is recognized that there is a common scope of applicability between that rule and the one proposed for export and import shipments (i.e. category 1 of Appendix P to Part 110). We encourage NRC to consider any implications either rulemaking on each other to ensure that the requirements of each do not conflict and that they are complimentary in order to achieve the necessary improvements to security of these materials in transport. Since Category 1 materials are covered in both proposed rules, NRC needs to ensure that any safeguards requirements from the enhanced security rule are taken into account in the export/import PR to meet the terms of notification (110.50) and other requirements (e.g. 10 CFR 2.390). The NRC should also consider whether there are safeguards implications regarding the licensee obligation to notify the importing country in 110.50.

## 3. Approval of Proposed Exports (110.42)

The determination as to which receiving countries have the appropriate technical and administrative capability, resources and regulatory structure to manage the material in a security manner should be made using an agreed set of standard criteria and should be made in advance of the effective date of the proposed rule. There is also a concern as to the timeliness of NRC review and approval for the issuance of export licenses. The NRC needs to consider alternatives if the demand for export licenses exceeds the capacity of the NRC to issue them in order to avoid the disruption of global trade.

## 4. Discrepancy within Terms of Proposed Rule

The proposed 110.50 (b)(4) states that a licensee authorized to export or import *material* listed in Appendix P is responsible for notifying the NRC and the importing country. Paragraph 110.50 (b)(4)(vii) requires information on the number of radioactive *sources* and their unique identifiers or a description of the sources. It is unclear how this information in 110.50 (b)(4)(vii) is to be reported if the material to be exported is not in the form of a sealed source and this needs to be addressed.

## 5. Import and Export of Disused Radioactive Sources

Paragraph 27 of the Basic Principles of the IAEA Code of Conduct on the Safety and Security of Radioactive Sources states that "every state should allow for the re-entry into its territory of disused sources if, in the framework of its national law, it has accepted that they can be

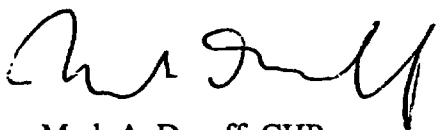
returned to a manufacturer authorized to manage the disused sources.” In the context of a very broad definition of radioactive waste, NRC has traditionally categorized what IAEA calls disused sources as radioactive waste which, under the existing 10 CFR 110.27(c), cannot be imported under a general license. To be consistent with the intent of the IAEA Code of Conduct, NRC should reconsider its regulatory position on disused sources and allow, under a general license, their importation for receipt by responsible and competent manufacturers to ensure they will be managed in a safe and secure manner.

6. Proposed Appendix P Activity Thresholds

Appendix P to the proposed revision to part 110 includes activity thresholds for both Category 1 and 2 in the units of both TBq and Ci. Converting from one system of units to the other does not result in the corresponding value in the table. This is problematic in the effort to demonstrate compliance with the table and NRC should adopt one system of units or provide clarification on how licensees are to address the issue of conversion.

CORAR appreciates the intent of this proposed rule and the opportunity to express these comments. Please contact us if there should be any questions or if any additional information is needed concerning these comments.

Sincerely,

A handwritten signature in black ink, appearing to read 'Mark A. Doruff', with a stylized flourish at the end.

Mark A. Doruff, CHP  
Council on Radionuclides and Radiopharmaceuticals

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